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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/937,513	09/25/2001	Amalio Cantoro	16696-7	2210

7590

05/09/2002

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EXAMINER

DELCOTTO, GREGORY R

ART UNIT	PAPER NUMBER
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1751

5

DATE MAILED: 05/09/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/937,513

Applicant(s)

CANTORO, AMALIO

Examiner

Gregory R. Del Cotto

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 September 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5. 6) ☐ Other: _____

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DETAILED ACTION

1. Claims 1-9 are pending. The preliminary amendment filed 9/25/01 has been entered.

Priority

2. Applicant has supplied a copy of a foreign priority document RM99 A 000205. However, no claim has been made in the oath for foreign priority under 35 USC 119 (a)-(d) to this document and foreign priority is not granted back to this date.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 4, 5, 6, and 9 recite the term "poloxamer". Note that, this is a tradename and is impermissible in claims. It is suggested that Applicant insert the chemical name of the surfactant material.

Claims 6-9 provides for the use of an ophthalmic solution, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

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Claims 6-9 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-4 and 6-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 99/27060 in view of Ellis et al (US 6,277,365).

'060 teaches contact lens cleaning aqueous solutions and multi-purpose aqueous solutions which include surfactant components in amounts effective in removing deposit material from a contact lens contacted with the composition and

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effective amounts of viscosity inducing components in amounts from about 0.05% to about 0.5% such as HPMC. See page 2, lines 19-35. The surfactant component is nonionic and preferably poly(oxyethylene)-poly(oxypropylene) block copolymers, etc. See page 3, lines 12-20. A suitable example includes poloxamer 407. See page 7, lines 20-27. The compositions may further comprise effective amounts of one or more additional components such as an antimicrobial component, a buffer component, chelating or sequestering component, a tonicity component, and the like and mixtures thereof. Suitable buffers includes sodium dibasic phosphate, etc. See page 12, lines 1-12. Suitable tonicity components include sodium chloride, etc. See page 13, lines 15-32.

'060 does not specifically teach the use of hyaluronic acid or a salt thereof or a composition containing hyaluronic acid or a salt thereof, a nonionic surfactant, and the other requisite components in the specific proportions as recited by the instant claims.

Ellis et al teach compositions and methods for treating a contact lens to placed on the eye with an aqueous composition comprising a quaternary nitrogen containing ethoxylated glycoside and a therapeutic agent. See Abstract. Suitable therapeutic agents include anionic polysaccharides, hyaluronic acid and salts thereof, etc. See column 3, lines 45-60.

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to use a therapeutic agent such as hyaluronic acid or a salt thereof in the contact lens cleaning composition taught by WO 99/27060, with a reasonable expectation of success, because Ellis et al teach that hyaluronic acid or a salt thereof

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acts as a therapeutic agent in a similar cleaning composition, and further, '060 teaches the use of optional components which would encompass therapeutic agents.

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to formulate a contact lens cleaning composition containing containing hyaluronic acid or a salt thereof, a nonionic surfactant, and the other requisite components in the specific proportions as recited by the instant claims, with a reasonable expectation of success and similar results with respect to other disclosed components, because the broad teachings of '060 in combination with Ellis et al suggest a contact lens cleaning composition containing hyaluronic acid or a salt thereof, a nonionic surfactant, and the other requisite components in the specific proportions as recited by the instant claims.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over WO 99/27060 in view of Ellis et al (US 6,277,365) as applied to claims 1-4 and 6-9 above, and further in view of WO 95/00615.

'060 and Ellis are relied upon as set forth above. However, '060 does not teach use of phosphoric acid as recited by instant claim 5.

'615 teaches compositions for treating contact lenses comprising a quaternary nitrogen-containing ethoxylated alkyl glycoside. See Abstract. The compositions may also include buffering agents such as phosphates, phosphoric acids, etc. See page 6, lines 5-15.

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to use phosphoric acid in the contact lens cleaning composition

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taught by '060, with a reasonable expectation of success, because '615 teaches the equivalence of phosphoric acid to phosphate salt buffering agents and '060 teaches the use of phosphate salt buffering agents.

Conclusion

4. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Remaining references cited but not relied upon are considered to be cumulative to or less pertinent than those relied upon or discussed above.

Applicant is reminded that any evidence to be presented in accordance with 37 CFR 1.131 or 1.132 should be submitted before final rejection in order to be considered timely.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gregory R. Del Cotto whose telephone number is (703) 308-2519. The examiner can normally be reached on Mon. thru Fri. from 8:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yogendra Gupta can be reached on (703) 308-4708. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9310 for regular communications and (703) 872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

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GRD

May 6, 2002

GREGORY DELCOTTO
PRIMARY EXAMINER

A handwritten signature in black ink, appearing to read "Gregory Delcotto", written in a cursive style.